EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

RESPONSIVE EXPERT REPORT OF MANSOOR M. AMIJI, PH.D. ON NON-INFRINGEMENT

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I, Dr. Mansoor M. Amiji, submit this Responsive Expert Report as follows:

1. My name is Mansoor M. Amiji.

2. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned district court patent litigation case, with case number 2:21-cv-10312-SJM-RSW. I am being compensated for my time in connection with this litigation at my standard consulting rate of $900 per hour. My compensation is not affected by the outcome of this matter.

3. I have been informed that Trutek has accused BlueWillow's NanoBio Protect® product of infringing claims 1, 2, 6 and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent"). I have reviewed the three reports served by Trutek and prepared by Dr. Edward Lemmo, Dr. Alexei Ermakov and Mr. Shane Burns, and have been asked to provide my opinions and analysis as to the matters addressed therein with respect to whether NanoBio Protect® satisfies each element of claims 1, 2, 6, and 7 (the "Asserted Claims") of the '802 Patent. My analysis and opinions provided herein are limited to the Challenged Claims, and I reserve the right to amend and/or update my analysis and opinions should Trutek assert additional claims in this litigation.

4. This report sets forth the opinions that I have formed based on the information available to me as of the date below. The opinions and facts set forth

in this report are based upon the information described in this report, as well as my analysis of the asserted patent, Trutek's expert reports, the state of the art at the time of the invention, as well as my knowledge and experience in the relevant field. It is my understanding that expert discovery is ongoing. I reserve the right to supplement or amend this report based on additional information made available to me, including in light of any expert reports or other responses to the subject matter addressed herein.

5. I expect to be called to testify at trial in the above-captioned action. If called upon, I am prepared to testify about my background, qualifications, and experience, as well as about the issues set forth in this report. If I am called upon to testify at trial, I may rely on exhibits and/or visual aids to demonstrate the bases for my opinions. I have not yet prepared any such exhibits or visual aids. I also reserve the right to provide a tutorial relating to the general topics contained in this report.

6. I am not currently and have not at any time in the past been an employee of BlueWillow. I have no financial interest in BlueWillow.

I. QUALIFICATIONS AND EXPERIENCE

7. I am an expert in the field of pharmaceutical sciences and drug formulation development and characterization. Specifically, I specialize in drug formulation development and targeted delivery of therapeutics, and I have been an

expert in this field since prior to July 7, 2008. I have relied upon my training, knowledge, and experience in the relevant art to form my opinions.

8. In 1988, I graduated with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, I received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University, under the supervision of Professor Kinam Park. My dissertation focused on biomaterials and water-soluble polymers. During my graduate studies at Purdue University, I took several pharmaceutics courses and had hands-on training in pharmaceutical formulation development and characterization.

9. After receiving my Ph.D. in 1992, I worked as a Senior Research Scientist for Columbia Research Laboratories (CRL) in Madison, Wisconsin. At CRL, I worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces.

10. I am currently the University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. I am also jointly appointed as a Professor of Chemical Engineering in the College of Engineering at Northeastern University. I am also currently an Affiliate Faculty Member in the

Department of Biomedical Engineering at Northeastern University. I have taught and carried out research in pharmaceutical sciences at Northeastern University since 1993, and from 2010 to 2016, I served as the Chairman of the Department of Pharmaceutical Sciences. In 2000, I was a Visiting Research Scholar in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT) in Cambridge, Massachusetts, in the laboratory of Professor Robert Langer.

11. As a tenured faculty member at Northeastern University, I have over 29 years of experience in teaching drug formulations to both graduate and undergraduate students. In theory and laboratory courses that I have taught and continue to teach, I extensively cover the manufacturing and composition of pharmaceutical formulations, delivery systems and pharmacokinetics. I also serve as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

12. I lecture extensively on various topics at the leading edge of modern pharmaceutical sciences, and I regularly attend numerous worldwide pharmaceutical conferences. I have been an invited speaker at national and international scientific conferences.

13. Over the course of my career, I have published extensively and am ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. I have coauthored over 60 book chapters and more than 350 peer

reviewed scientific articles. I am also an inventor on several issued United States patents. The topics of these materials including the design and development of pharmaceutical dosage forms, pharmacokinetics, drug metabolism, dose delivery and controlled research systems and the use/formulation of related excipients and methods. I have been involved in and consulted on multiple projects over the years both in industry and academia about the aforementioned topics. To that end, I have taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics.

14. I have served as a grant reviewer for the National Institutes of Health, the Department of Defense, the United States Department of Agriculture, and the American Chemical Society. I am a member of several professional and industrial societies, including the American Association of Pharmaceutical Sciences (AAPS) and the Controlled Release Society (CRS), and have participated as a reviewer for more than 50 scientific journals.

15. I have also received a number of professional awards and honors, including the Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology in 2006; a Fellowship and Meritorious Manuscript Award from the AAPS in 2007; the Tsuneji Nagai Award from the CRS in 2012; the Northeastern University School of Pharmacy Distinguished Alumni

Award in 2016; and Purdue University College of Pharmacy Distinguished Alumni Award in 2019. Over the course of my career, I have advised numerous post-doctoral associates, doctoral students, master's students, visiting scientists, and research fellows.

16. I am a founder and scientific advisor to many pharmaceutical companies, including Nemucore Medical Innovations and Targagenix, Inc., which have licensed our patents on lipid-based drug delivery systems and is in the process of developing commercial products.

17. I was appointed as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2007 and serve as a long-term member of the Association. I am also a Fellow of the Controlled Release Society (CRS) since 2014 and serve on the Scientific Advisory Board of the CRS. I have also served as a permanent member of the National Institutes of Health's grant review panel and many other public funding agencies in the U.S. and across the world. I am an Editor of the journal Drug Delivery and Translational Research and Associate Editor of several peer-reviewed journals and on the editorial board of about a half dozen other scientific journals.

18. Additional details concerning my background, training and experience are contained in my current *Curriculum Vitae*, attached as Exhibit 1.

19. Based on my education, training, and experience, including my research expertise in pharmaceutical product development and drug formulation development of over 29 years, including in the July 7, 2008 time frame, I am qualified to provide technical analysis and opinions regarding the subject matter of this case and the '802 Patent.

20. The matters in which I have testified in the past four years include:

- *iCeutica Private, LTD et al. v. Lupin Limited et al.*, C.A. No. 1:14-cv-01515-SLR-SRF (D. Del.)
- *Mylan Pharmaceuticals Inc. v. Allergan, Inc.*, C.A. No. IPR2016-01127, -1128, -1129, -1130, -1131, -1132 (PTAB)
- *Lipocine, Inc. v. Clarus Therapeutics, Inc.*, Patent Interference No. 106,045 (McK)
- Cadence Pharmaceuticals Inc., et al. v. InnoPharma Licensing LLC, et al., C.A. No. 1:14-cv-01225-LPS (D. Del.)
- *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, C.A. No. 2:2015-cv-06934 (D.N.J.)
- R*eckitt Benckiser LLC v. Aurobindo Pharma Limited*, C.A. No. 14-cv-1203-LPS (D. Del.)
- *AMAG Pharmaceuticals, Inc. v. Sandoz, Inc.*, C.A. No. 16-1508-PGS-LHG (D.N.J.)
- *Alcon Research, Ltd. v. Watson Laboratories. Inc.*, C.A. No. 16-129-LPS-SRF (D. Del.)
- *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*, C.A. No. 16-988-LPS (D. Del)
- *Almirall, LLC v. Taro Pharmaceutical Industries Ltd.*, C.A. No. 17-663-JFB-SRF (D. Del.)
- *Galderma Labs. LP v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 17-1783-RGA (D. Del.)
- *FWK Holdings LLC v. Shire PLC et al.*, C.A. No. 16-cv-12653-ADB (Lead) and No. 17-cv-10050-ADB (Consol.) (D. Mass.)
- *Impax Laboratories, Inc., v. Zydus Pharmaceuticals Inc & Cadilla Healthcare*, C.A. No. 17-cv-13476 (SRC)(CLW) (D.N.J)

- *Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.*, C.A. No. 18-cv-00823 (CFC) (D. Del.)
- *Vifor Fresenius Medical Care Renal Pharma Ltd. et al v. Lupin Atlantis Holdings SA et al*, C.A. No. 18-cv-00390 (MN) (D. Del.)
- *Pharmacyclics, et al., v. Cipla, et al.*, C.A. No. 1:18-cv-00192-CFC (Consol.) (D. Del.)
- *Lipocene, Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 1:19-cv-622-WCB (D. Del.)
- *Thorne Labs v Trustees of Dartmouth*, C.A. No. IPR2021-00268 (PTAB).

21. Based on my training, teaching, consulting, and research expertise in the pharmaceutical product development and drug delivery over the last 29 years, I am qualified to serve as an expert witness for this lawsuit.

II. MATERIALS AND OTHER INFORMATION CONSIDERED

22. In forming the opinions expressed in this report, I relied upon my education and experience in the relevant field of the art, and have considered the viewpoint of a person having ordinary skill in the relevant art as of the Priority Date of the ’802 Patent. I have also considered the information provided in the Lemmo report dated June 27, 2022, the Ermakov report dated January 11, 2021, and the Burns report dated January 18, 2021, in addition to the other information and references described and discussed herein.

III. UNDERSTANDING OF LEGAL PRINCIPLES

23. I am not an attorney. For purposes of this report, I have been informed about certain aspects of the law that are relevant to my opinions, as described below.

A. Claim Construction

24. I have been informed that a claim must be construed under the *Phillips* standard. Under that standard, words of a claim are given their plain and ordinary meaning as understood by person of ordinary skill in the art at the time of invention, in light of the specification and prosecution history, unless those sources show an intent to depart from such meaning, as well as pertinent evidence extrinsic to the patent.

25. For purposes of this Opening Report, I applied the plain and ordinary meaning of each term to a person of ordinary skill in art ("POSA") at the time of the alleged invention unless explicitly stated otherwise. I understand that the parties have not yet completed claim construction disclosures and that the Court has not construed any of the claim terms of the ’802 Patent. I reserve the right to amend and/or update my analysis and opinions provided herein to the extent that any party offers a different claim construction and/or to the extent that the Court construes any such claim terms.

B. Infringement

26. I have been informed that for BlueWillow to be liable for direct infringement, it must be shown that BlueWillow has made, used, sold, offered for sale, imported into the United States a product that meets each and every requirement of the claim (either literally or under the doctrine of equivalents).

Based on reports provided by Trutek, I have been informed and understand that Trutek asserts that NanoBio Protect® infringes the asserted claims under a literal infringement theory, and not under the doctrine of equivalents. As such, I have not considered the doctrine of equivalents in my analysis but reserve the right to do so should it be necessary in the future.

27. I have been informed that literal infringement requires that every limitation set forth in a claim must be found in an accused product. I am also informed that direct infringement requires a party to perform each and every step or element of a claimed product or method. I have also been informed that for purposes of any infringement analysis, the comparison is between the properly construed claims and the accused product.

IV. SUMMARY OF OPINIONS

28. For purposes of this report, I have been asked to provide my analysis and opinions concerning the Trutek's assertion that NanoBio Protect® infringes asserted claims 1, 2, 6 and 7 of the '802 Patent. More specifically, I have been asked to provide my analysis and opinions in response to the testing conducted by Dr. Alexei Ermakov and Mr. Shane Burns on behalf of Trutek, as well as the opinions and analysis offered by Dr. Edward Lemmo on behalf of Trutek concerning infringement of the Asserted Claims of the '802 Patent.

29. I reserve the right to respond to any additional opinions or evidence offered by experts on behalf of Trutek concerning the alleged infringement of the Asserted Claims of the ’802 Patent. Further, I reserve the right to supplement this report to address any claim construction positions raised by Trutek and/or in response to any order issued by the Court on claim construction.

30. The opinions set forth in this report are based on my education, knowledge and experience in the area over the past 29 years.

31. In my opinion, NanoBio Protect® does not satisfy each of the elements of claims 1, 2, 6 and 7 of the ’802 Patent, and Trutek and its retained experts have not demonstrated that NanoBio Protect® satisfies each element of claims 1, 2, 6 and 7 of the ’802 Patent.

V. ASSERTED CLAIMS THE ’802 PATENT

32. The Asserted Claims of the ’802 Patent are listed below:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

> 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivates the particulate matter and renders said particulate matter harmless.
>
> 6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.
>
> 7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

VI. PERSON OF ORDINARY SKILL IN THE ART

33. As explained in my Opening Report, I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the alleged invention, the sophistication of the technology, the type of problems encountered in the art, and the prior art solutions to those problems.

34. In determining the characteristics of a hypothetical person of ordinary skill in the art of the ’802 Patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication

of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the ’802 Patent. Finally, I placed myself back in the relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

35. It is my opinion that the art of the subject matter of the ’802 Patent is a pharmaceutical formulation. Based on the materials I have considered, my own experience, and the knowledge required to design pharmaceutical formulation including the use of excipients, I came to the conclusion that the characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team — including a chemical engineer, microbiologist, or polymer chemist — and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

VII. NANOBIO PROTECT® DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '802 PATENT

36. For the reasons explained below, it is my opinion that Trutek and its retained experts have not demonstrated that NanoBio Protect® satisfies each element of Asserted Claims 1, 2, 6 and 7 of the '802 Patent.

A. Ermakov and Burns Testing

37. In his report, Dr. Lemmo indicates that he relied on testing conducted by Dr. Ermakov and Mr. Burns, which purportedly demonstrate that NanoBio Protect® and Trutek's NasalGuard products exhibit an electrostatic charge "of the same order of magnitude." I have reviewed the reports prepared by Dr. Ermakov and Mr. Burns and the testing described therein, and disagree with the conclusions reached by Dr. Lemmo on the basis of those reports for the reasons that follow. *E.g.*, Lemmo Report at 3, 9-10.

38. Dr. Ermakov's testing purports to evaluate or measure the amount or magnitude of surface electrostatic charge of NanoBio Protect® and Trutek's NasalGuard after application of the test products to plain sheets of standard printer paper. Similarly, Mr. Burns' testing also purports to evaluate or measure the amount or magnitude of surface electrostatic charge of the test products, but after application to a piece of pig skin, as opposed to printer paper.

39. Based on my experience and knowledge in the relevant field, it is my opinion that there are numerous flaws in how the tests were conducted, the test

results and methods are not indicative of or relevant to how NanoBio Protect® operates when used by individuals and the issue of whether NanoBio Protect® satisfies the elements of the asserted claims, and the test results themselves show significant discrepancies. In addition, there is no evidence that Trutek's NasalGuard products used as controls in the studies meet the limitations of the asserted claims. For each of these reasons, in my opinion, a person of ordinary skill in the art reviewing the Ermakov and Burns testing would not understand the test results to establish that NanoBio Protect® satisfies the claim limitations and/or infringes the asserted claims of the '802 Patent.

40. As an initial matter, both of the Ermakov and Burns tests measure the conductivity of the test formulations, not surface electrostatic charge. I also note that the asserted claims of the '802 patent do not even require a surface charge for the formulation, let alone a particular surface charge or range that would be necessary to achieve result of electrostatically attracting and inhibiting harmful particulate matter from infecting an individual. Moreover, neither of the tests include any calibration standards or any other procedure for validating the methods. Thus, there is extremely limited information, if any, that can be taken from these tests to determine whether NanoBio Protect® or the NasalGuard products used as controls exhibit a surface charge that is sufficient to practice the elements of the asserted claims. For each of these reasons, in my opinion, a person

of ordinary skill in the art would understand that the purported calculations of the surface charge of NanoBio Protect® and NasalGuard alone are meaningless within the context of the claimed invention and do not establish that either product satisfies the elements of the asserted claims.

41. In the Ermakov test, there is no mention of how much of the sample is actually put on the paper before testing. Additionally, the sample was left under ambient conditions where it could be dried or contaminated. None of these considerations were included in the analysis.

42. In addition, neither of the Ermakov or Burns tests were conducted under circumstances that would mimic real life use of NanoBio Protect® in individuals. Both experiments were performed at room temperature, which is significantly lower than body temperature. Similarly, testing the surface charge of NanoBio Protect® as applied on paper and/or a piece of dried pig skin is not indicative or predictive of how the product will operate on human nasal skin or tissue. In this regard, I disagree with Dr. Lemmo's assertion that the "use of pig skin is more predictive than paper regarding how the product would behave on human skin", particularly in view of how Mr. Burns conducted the experiment. As tested, the pig skin was completely dry, which is unlike the typical nasal environment, which has blood supply and is generally very moist. Likewise, the excised portions of pig skin used by Mr. Burns do not accurately replicate *in vivo*

conditions in humans, particularly with respect to different barrier properties, lack of blood vessels, and high variability among skin samples.

43. Finally, in my opinion, the results of the Ermakov and Burns testing are highly variable and as such, would not realistically inform a person of skill in the art as to the nature or magnitude of any surface charge exhibited by NanoBio Protect®.

44. For example, with respect to the Ermakov testing, I note that paper is not conductive, but it does have a charge. The paper has an average surface charge of 6.67×10^{-15} Coloumbs per sq. inches and the NanoBio Protect® solution has a surface charge of 4.35×10^{-14} Coloumbs per sq. inches. Both of Trutek's products NasalGuard Airborne Blocker and NasalGuard Misting Spray gave significantly higher charge values of 8.32×10^{-14} Coloumbs per sq. inches and 7.19×10^{-14} Coloumbs per sq. inches than the NanoBio product.

45. With respect to the Burns testing, I note that while the 3 experiments conducted with Trutek's NasalGuard gave fairly similar results (0.24 nC, 0.27 nC, 0.24 nC for an average of 0.25 nC), the 3 experiments conducted with NanoBio Protect® gave an extremely wide range of results (0.85 nC, 0.09 nC, 0.35 nC for an average of 0.43 nC). The high variability in these results suggest to a person of skill in the art that the experiment was flawed and unreliable.

46. Moreover, the results between the Ermakov and Burns experiments are inconsistent. More specifically, Burns reports that NanoBio Protect® exhibits a higher charge per square centimeter (0.006 nC/cm^2) than NasalGuard (0.003 nC/cm^2). However, Ermakov reports the opposite result, with NasalGuard (8.32x 10^{-14} and 7.19 $x10^{14}$ Coloumbs per sq. inches) exhibiting a higher charge per square inch than NanoBio Protect® (4.35x 10^{-14} Coloumbs per sq. inches).

47. The inconsistency in the experimental results is even more extreme when taking into account Mr. Burns' prior testing of the NasalGuard product. In prior experiments applying the same test procedure using pig skin, Mr. Burns reported a charge per square centimeter of 0.146 for nC/cm^2 for Trutek's Nasal Guard. Exhibit 2 (July 30, 2019 Technical Report prepared by Shane Burns at page 5 (reporting surface charge measurements of NasalGuard)). This is an almost 100-fold difference from the NasalGuard results Mr. Burns obtained and reported in his January 18, 2021 report comparing NasalGuard with NanoBio Protect®.

B. NanoBio Protect® Does Not Satisfy Each Element of the Asserted Claims of the '802 Patent

48. Additionally, I disagree with the overall "findings and conclusions" listed by Dr. Lemmo at pages 1-3 of his report and his ultimate opinions that NanoBio Protect® satisfies each of the elements of asserted claims 1, 2, 6 and 7 of the '802 Patent.

49. Independent claim 1 recites a method for "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein a "formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and "electrostatically attracting the particulate matter to the thin film." It is my understanding that each of these claim elements must necessarily occur during use of the accused product to demonstrate infringement.

50. Independent claim 2 is similar in that it recites a formulation for "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein a "formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and once applied, the formulation "electrostatically attracts the particulate matter to the thin film." Likewise, it is also my understanding that the accused product must necessarily perform or exhibit each of these claim elements to demonstrate infringement.

51. Asserted claims 6 and 7 are dependent claims that depend from claim 2. As such, it is my understanding that each of the elements of claim 2 must also be met in order to demonstrate infringement of claims 6 and 7 of the '802 Patent.

52. Even if a person of skill in the art were to accept the results of the Ermakov and Burns testing as demonstrating that NanoBio Protect® exhibits an electrostatic charge when "applied to skin or tissue of nasal passages" of an individual (a point which I dispute for the reasons explained above), the Ermakov

and Burns testing does not demonstrate that the purported electrostatic charge operates to "inhibit[] harmful particulate matter from infecting an individual" or "electrostatically attracts the particulate matter to the thin film." More specifically, the Ermakov and Burns testing bears no relation to whether the purported electrostatic charge exhibited by NanoBio Protect® actually operates to: (1) inhibit infection in an individual, or (2) is sufficient to electrostatically attract particulate matter to the thin film, or (3) the thin film creates an impermeable barrier. This is particularly true given that the Ermakov and Burns testing was conducted on a piece of paper and dried pig skin, neither of which are representative or predictive of what would occur in the nasal passages of an individual.

53. I also disagree with Dr. Lemmo's assertion that "germs are 'bound' to the nano-droplets" of NanoBio Protect®. Lemmo Report at 11. Dr. Lemmo does not provide a citation for this specific assertion, but does reference a portion of BlueWillow's website elsewhere in his report. In reaching his opinion that "germs are 'bound' to the nano-droplets" of NanoBio Protect®, Dr. Lemmo appears to mischaracterize BlueWillow's website. The portion of the website cited by Dr. Lemmo states: "And lastly, when bound to nano droplets, BZK is non-irritating to the skin." Lemmo Report at 10; Exhibit D. This statement clearly refers to BZK being "bound" to the nano droplets, and not any "germs." Dr. Lemmo cites no other materials or information concerning what may or may not

be "bound" to the NanoBio Protect® nano droplets, apart from the citation above indicating that BZK (and not germs) is bound to the nano droplets.

54. I also disagree with Dr. Lemmo's assertion that when administered, NanoBio Protect® "forms a thin film that adheres to the skin or tissue of nasal passages." Notably, Dr. Lemmo does not rely on any test results to demonstrate that this element of the asserted claims is met by NanoBio Protect®. Instead, Dr. Lemmo makes the unsupported assertion that "[i]f that were not the case, the liquid would instantly drip out of the user's nose," noting that BlueWillow's website indicates that "the droplets persist on the skin for four or more hours." Lemmo Report at 11. Nowhere does the material cited indicate that when applied, NanoBio Protect® forms a thin film on the nasal passages, let alone a thin film that persists for hour hours or operates to electrostatically attract and inhibit particulate matter from infecting an individual by creating a permeability barrier.

55. In this regard, I note that Exhibit E to Dr. Lemmo's report (excerpt from BlueWillow website) indicates that "NanoBio Protect's nanodroplets are small enough to reach germs that hide in the deep layers of skin, but big enough to prevent absorption through the skin into the bloodstream." As such, a person of ordinary skill in the art would understand that the size of the NanoBio Protect® nanoemulsion facilitates penetration into the deep layers of the skin (hair follicles,

sebaceous glands, sweat glands, etc.) and does not work by forming a thin, impermeable barrier on the surface of the skin in and around the nasal passages.

56. Finally, I also disagree with Dr. Lemmo's assertion that NanoBio Protect® satisfies the claim element of "holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film."

57. In support of his opinion, Dr. Lemmo appears to again rely on the results of the Ermakov and Burns testing that purport to demonstrate that NanoBio Protect® exhibits an electrostatic charge, concluding that based on this purported electrostatic charge, the NanoBio Protect® nano droplets necessarily electrostatically attract particulate matter (e.g., germs), holding them in place. As explained above, the Ermakov and Burns testing does not demonstrate that NanoBio Protect® operates in this manner.

58. In addition, Dr. Lemmo does not address the claim element that requires "adjusting the adhesion of the thin film" other than to assert that the "product forms a thin film that adheres to the skin or tissue of his nasal passages," a point I dispute as explained above. Nor does Dr. Lemmo address the claim element that requires "adjusting the cohesion of the formulation to provide adequate impermeability to the thin film" other than by asserting that the "droplets

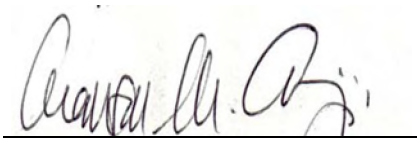
significantly hydrate skin to avoid dryness or cracking that can allow germs in." A person of ordinary skill in the art would understand that a formulation such as NanoBio Protect®, which purports to alleviate dryness in the nasal passage, does not necessarily do so as a result of any "adjustment" in the "cohesion of the formulation" or by existing as an impermeable thin film on the nasal passages.

VIII. CONCLUSION

59. For the aforementioned reasons, in my opinion, NanoBio Protect does meet every element of claims 1, 2, 6 and 7 of the '802 Patent and therefore, does not infringe the Asserted Claims of the '802 Patent.

Date: August 15, 2022

Respectfully submitted,



Mansoor M. Amiji, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that on **August 15, 2022**, I caused the foregoing document to be served via email and First Class Mail on:

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